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| 10/755,996 | 01/13/2004 | Peter M. Bonutti | 780-A03-021-5 | 1472 |
| 33771 | 7590 | 05/10/2010 | EXAMINER | |
| PAUL D. BIANCO | | | HOFTMAN, MARY C | |
| Fleit Gibbons Gutman Bongini & Bianco PL | | | ART UNIT | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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| Office Action Summary | Application No. 10/755,996 | Applicant(s) BONUTTI, PETER M. |
| | Examiner MARY HOFFMAN | Art Unit 3733 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 05 February 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,4-10,13,15,19,30-32,35,37-39,41 and 46-50 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,4-10,13,15,19,30-32,35,37-39,41 and 46-50 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 13 January 2004 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-646)
 3) Information Disclosure Statement(s) (PTO/SB/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
 5) Notice of Informal Patent Application
 6) Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 1, 4-10, 13, 15, 19, 30-32, 35, 37-39, 41 and 46-50 are rejected under 35 U.S.C. 101 because they are drawn to non-statutory subject matter. In claim 30, line 20, applicant positively recites part of a human, *i.e.* "the implant being fixed to only the first bone". In claim 41, line 15, applicant positively recites part of a human, *i.e.* "the implant being fixed to only the first bone". Thus claims 1, 4-10, 13, 15, 19, 30-32, 35, 37-39, 41, are 46-50 include a human within their scope and are non-statutory.

A claim directed to or including within its scope a human is not considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. *In re Wakefield*, 422 F.2d 897, 164 USPQ 636 (CCPA 1970).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-10, 13, 15, 19, 30-32, 35, 37-39, 41 and 46-50 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 30, lines 7-8, the claim recites "the implantable device having no fastener." In line 16, the claim recites a "fastener". The claim is drawn to an "implantable device" (see preamble). It is unclear how the implantable device can comprise a fastener (line 16) and also have no fastener (line 8).

In claim 41, line 6, the claim recites "the implantable device having no fastener." In line 11, the claim recites a "fastener". The claim is drawn to an "implantable device" (see preamble). It is unclear how the implantable device can comprise a fastener (line 11) and also have no fastener (line 6).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 8-9, 13, 15, 19, 30-32, 35, 37-39, 41, 43-45, and 47-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Henderson et al. (U.S. Patent No. 6,066,175).

Stone discloses an implantable device capable of changing a spatial relationship between a first bone and a second bone from a first position to a second position, comprising a first surface capable of abutting the first bone; a second surface connected to the first surface capable of abutting the second bone in the wide position and the narrow position; and a body interconnecting the first surface and the second surface, the first surface maintaining an equal distance from the second surface when moving from the wide position to the narrow position (the device shown in FIG. 3C and 4A is capable of being inserted on its side and then be rotated 90 degrees). The implantable device is capable of being rotated via the pin about an axis to move between the wide position and the narrow position and not move longitudinally along the axis when moving from the wide position to the narrow position. The device comprises a bone growth promoting material (col. 6, lines 60-61). The implant is adapted to one connected to only one of the bones. The first surface tapers to form a pointed edge with the second surface. A side surface corresponding to the outer surface of the bone connects the first and second surfaces. The body has an open cellular structure to provide cavities in which bone can grow through (col. 6, lines 34-36). The body is made of a biocompatible metallic material (col. 6, lines 44-46). At least some of the cavities contain a bone growth promoting material. (col. 7, lines 8-14).

Stone discloses the claim invention except for 1.) the device being coated with a bone growth promoting material including a bone morphogenic protein; and 2.) a channel extending through both the first major surface and side surface, a second channel extending through both s second major surface and side surface, and screws

angularly disposed in the channels and nested in the side surface. 3.) Stone also fails to disclose the second surface having no fastener to fix the second surface to the second bone.

1.) Michelson discloses using a coating of bone growth promoting material, wherein the bone growth promoting material includes a bone morphogenic protein, in order to promote bioactive fusion (col. 9, lines 20-24). It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with the coating of Michelson in order to promote bioactive fusion.

2.) Henderson et al. disclose an implantable device including a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels and nested in the side surface in order to provide means of attachment to the bone/additional bone fixation (ref. #48, 49, FIGS. 8-9, col. 9, lines 29-31).It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone with a first channel extending through the first major surface and side surface, a second channel extending through a second major surface and side surface, and first and second screws angularly disposed in the channels and nested in the side surface in view of Henderson in order to provide means of attachment to the bone/additional bone fixation.

3.) It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and

Henderson et al. surface having no fastener to fix the second surface to the second bone, since such a modification would have been an obvious omission of a part. It can be seen in the other embodiments of Stone (e.g. 1A) that the device does not require fasteners, and the fasteners are only present to allow additional fixation.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and Henderson et al. (U.S. Patent No. 6,066,175) further in view of Jefferies (U.S. Patent No. 4,394,370).

Stone in view of Michelson and Henderson disclose the claimed invention except for the coating being apatite compositions such as demineralized bone powder and collagen.

Jefferies teaches both demineralized bone powder and collagen as materials to induce the formation of osseous tissue (Abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have the coating of the Stone in view of Michelson and Henderson to include demineralized bone powder and collagen in view of Jeffries, since those materials are well known in the art of bone fusion as materials to induce the formation of osseous tissue.

Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (U.S. Patent No. 6,008,433) in view of Michelson (U.S. Patent No. 5,609,635) and

Henderson et al. (U.S. Patent No. 6,066,175) further in view of Zdeblick et al. (U.S. Patent No. 5,669,909).

Stone in view of Michelson and Henderson disclose the claimed invention except for using tantalum.

Zdeblick et al. teaches using porous tantalum in implants to allow bone ingrowth.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Stone in view of Michelson and Henderson using tantalum in view of Zdeblick et al. to allow bone ingrowth.

Response to Arguments

Applicant's arguments filed 02/05/2010 have been fully considered but they are not persuasive.

Regarding the rejection under 35 U.S.C. 101, it is noted that the claims are positively claiming that the implant is being fixed to the bone. To avoid a rejection under 35 U.S.C. 101, Applicant can amend the claims to state the "implant configured to be fixed..."

Regarding the rejection under Stone in view of Michelson and Henderson et al., it is noted that the device of the combination is capable as being used as claimed, by placing the device in the space between the first and second bones. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

In addition, Applicant's argument that the Stone device requires that both surfaces engage the bone "despite the wording" of Stone is unpersuasive. The Stone reference clearly states that "at a minimum, at least one of the principal surfaces 112, 114 is adapted, at least in part, to engage mechanically a surface or surfaces thereto..." The examiner is not persuaded by Applicant's argument that one would read the plain and unambiguous meaning of the language in Stone and understand a different meaning, *i.e.* that the principal surfaces of the implant must be fixed to both surfaces of the bone.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Mary C. Hoffman/
Examiner, Art Unit 3733
/Eduardo C. Robert/
Supervisory Patent Examiner, Art Unit 3733